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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,359	09/10/2004	Johan Bernard Ubbink	115808-504	5698
29157	7590	04/29/2009	EXAMINER	
K&L Gates LLP			BADR, HAMID R	
P.O. Box 1135				
CHICAGO, IL 60690			ART UNIT	PAPER NUMBER
			1794	
			NOTIFICATION DATE	DELIVERY MODE
			04/29/2009	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

***Advisory Action***

Applicants' amendment filed on 4/8/2009 has not been entered.

The amendment is not entered given that the amendment to claims 1 and 11 raises new issues that would require further consideration and search. While the group of inert carbohydrates consisting of maltodextrins, starches, low molecular weight sugars, and hydrocolloids is supported by the instant specification, their inclusion in claims 1 and 11 raise new issues the would require further consideration and search.

Further, the amendment is not being entered given that it raises new issues under 35 U.S.C 112 second paragraph.

Claim 1 is indefinite for "where in the inner matrix contains 40%-70% by weight of total dry matter, of at least one inert carbohydrate". It is not clear what is meant by the whole phrase. It is unclear what the applicant regards as the invention.

Claim 11 is indefinite for "mixing a first preparation of microorganisms and 40%-70% by weight of total dry matter of at least one inert carbohydrate". It is not clear what is meant by the whole phrase. It is unclear what the applicant regards as the invention.

Claims 1, 3, 5-14 remain rejected.

***Response to Arguments***

Applicants' arguments have been thoroughly reviewed. These arguments are not deemed persuasive.

A. Rejection under 35 U.S.C. 112(1):

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1. Applicants argue that the phrase “drying the first preparation to form particles, mixing the particles and further components” which is recited in claim 11 is supported by the specification.

a. Applicants have referred to page 4 line 35 to page 5 line 3 of the instant specification. Page 4 line 35 to page 5 line 3 is a reference to the viability of organisms, and does not concern drying and mixing of further components.

The disclosure at page 11; lines 14-33 does not include any phrase as mentioned above. However, while the specification discloses that particles containing “microorganisms” can include inert carbohydrates and can be dried, there is no disclosure of the broad recitation of “drying the first preparation to form particles, mixing the particles and further components”.

2. Applicants argue that claims 1, 5-7, and 9 which have been rejected under 35 U.S.C. 102(b) as being anticipated by US 5,480,641 (Casas-Perez), are not anticipated due to the amendments made to claim 1.

a. It should be realized that ‘641 (Casas) uses whey powder to make pelleted probiotics. It is also noted that a regular whey powder contains about 70% lactose on dry weight basis and a whey concentrate contains about 45-50% lactose on dry weight basis. Therefore, the carbohydrate content of the matrix is about 45%-70% which overlaps the presently claimed range.

The number of microorganisms per gram of whey powder, as disclosed by Casas, also overlaps with range as presently claimed. See Example 1, line 28).

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The water activity of the pellets of below 0.3 is inherent in the pellets. The inherency is explained by the nature of the probiotic organisms. The probiotic organisms will not have viability in the pellets if the water activity is over 0.3. See data in Table 1 (Col. 4). The limitation of pellet volume is also anticipated by Casas. Casas discloses the range of pellet volumes as 0.01-0.26 cm<sup>3</sup> (mesh no. 8 has a length of 2.38 mm, and mesh ¼ inch has a length of 6.35 mm. Assuming a cubic shape, the volumes of the pellets will be in the range above.) The pellet volume as presently claimed is included in the range as disclosed by Casas.

3. Applicants argue that Casas does not disclose the coating of the particles.

a. Casas discloses an oil coating for the pellets. See third paragraph of Example 1. Casas discloses another embodiment in which the microorganisms are mixed with the whey powder while they are mixed with the oil. See Example 2. The oil component of the pellets will protect the pellet from moisture and oxygen and in that capacity it will function as a coating.

Therefore Casas anticipates claim 1 as currently amended.

4. Applicants argue that Okonogi et al. (R2) in view of Klapwijk et al. (R3) and Van Lengerich (R4) alone or in combination fail to disclose or suggest every element of the present (1, 3, 5-14 claims) claims.

a. R2 discloses basically all features of the presently claimed invention including the sugar/starch matrix as presently claimed, however it is silent on the water activity of the pellets. R3 discloses that lactic acid bacteria are supported when the water activity of the composition is 0.3 or less. This water activity is presently claimed in claim 1. R4

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discloses a product that contains encapsulated live organisms. The coating of the pellets is discussed in Example 2 and 3 (page 35 and 36). Dimensions of the pellets are also disclosed by R4. Therefore, it would be obvious to make pellets (sugar/starch) containing live microorganism having pellet volume as presently claimed and coat them to protect the microorganism from environmental moisture and oxygen. Please refer to the pending Office action under rejections by R2 in view of R3 and R4.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

5. Applicants argue that claims 11-12 as amended are not obvious over Casas (R1).

a. Please refer to paragraph 2a above for the disclosure by R1 and how R1 anticipates the presently amended claim 1. However, since Casas uses lyophilized cells and the plasticizer used is oil, a drying stage as required by products containing water is not disclosed by Casas. It would be obvious to include a drying stage when the fermentation broth containing microorganisms are mixed with the matrix and pelleted. The sensitivity of lactic acid bacteria to high water activity is known to those of skill in the art. The remedy of drying will of course be obvious to an artisan.

Claims 1, 3, 5-14 remain rejected.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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